




COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine

A quick reference to dosing, dilution, and storage of formulations¹

	COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine Multiple-Dose Vial	COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine Multiple-Dose Vial	COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine Multiple-Dose Vial
Vial colour	 Vials with Gray Cap/Label Border	 Vials with Orange Cap/Label Border	 Vials with Maroon Cap/Label Border
Age range	12 years and older	5 to <12 years	6 months to <5 years
Can be used for primary series	YES	YES	YES
Can be used for booster dose	YES	YES	NO
Dilution required	No	Yes	Yes
Amount of diluent required per vial (0.9% Sodium Chloride Injection, USP)	DO NOT DILUTE before use	1.3 mL per vial	2.2 mL per vial
Number of doses per vial*	6 doses per vial	10 doses per vial (after dilution)	10 doses per vial (after dilution)
Dose amount	30 micrograms per dose (15 mcg of Original and 15 mcg of Omicron BA.4/BA.5)	10 micrograms per dose (5 mcg of Original and 5 mcg of Omicron BA.4/BA.5)	3 micrograms per dose (1.5 mcg of Original and 1.5 mcg of Omicron BA.4/BA.5)
Dose volume	0.3 mL per dose	0.2 mL per dose	0.2 mL per dose
Storage conditions			
ULT freezer storage time (-90 to -60°C)	18 months after manufacturing date printed on vial label	18 months after manufacturing date printed on vial label	18 months after manufacturing date printed on vial label
Freezer storage time (-25 to -15°C)	Do not store at -25 to -15°C	Do not store at -25 to -15°C	Do not store at -25 to -15°C
Refrigerated storage time (2 to 8°C) (within the expiry date)	10 weeks	10 weeks	10 weeks
Room temperature storage time (8 to 25°C)	12 hours prior to first puncture (including any thaw time)	12 hours prior to dilution (including any thaw time)	12 hours prior to dilution (including any thaw time)
After first puncture (2 to 25°C)	Discard after 12 hours	Discard after 12 hours	Discard after 12 hours
Expiry date	18 months after manufacturing date printed on vial label	18 months after manufacturing date printed on vial label	18 months after manufacturing date printed on vial label

ULT: ultra-low temperature.

Adapted from the COMIRNATY Original & Omicron BA.4/BA.5 Product Monograph¹

* Low dead-volume syringes and/or needles can be used to extract 6 or 10 doses from a single multiple-dose vial. If standard syringes and needles are used, there may not be sufficient volume to extract 6 or 10 doses from a single multiple-dose vial.

COMIRNATY® Original & Omicron BA.4/BA.5 (COVID-19 mRNA Vaccine, Bivalent [Original and Omicron BA.4/BA.5]) is indicated for active immunization against coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 6 months of age and older. The safety and effectiveness of a primary vaccination course of COMIRNATY Original & Omicron BA.4/BA.5 for individuals 6 months of age and older and booster dose of COMIRNATY Original & Omicron BA.4/BA.5 for individuals 5 years of age and older are inferred from studies which evaluated the primary series and booster vaccination with COMIRNATY and supported by studies of a booster dose of COMIRNATY Original & Omicron BA.4/BA.5 in individuals 6 months of age and older.¹ Marketing authorization has been issued with Terms and Conditions that need to be met by the Market Authorization Holder to ascertain the continued quality, safety and effectiveness of the vaccine.

For more information on COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine, and complete dosing instructions, please see the respective Product Monograph and go to [CVDvaccine.ca](https://www.cvdvaccine.ca)

To report product quality complaints or for more detailed instructions, please contact Pfizer Customer Service at **1-833-VAX-COVI (1-833-829-2684)**.

To report a side effect following immunization, please contact your local health unit or Pfizer Safety Department by calling 1-866-723-7111 or by fax at 1-855-242-5652, or visit www.pfizersafetyreporting.com.

Despite its official name, Canada may continue to receive vials of the vaccine labelled as Pfizer-BioNTech COVID-19 Vaccine.

For more information:

Please consult the COMIRNATY Original & Omicron BA.4/BA.5 Product Monograph at <https://www.pfizer.ca/en/our-products/comirnaty-original-omicron-ba4-ba5-covid-19-mrna-vaccine-bivalent-original-and-omicron-ba4-ba5> for contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use. The Product Monograph is also available upon request by calling **1-833-VAX-COVI (1-833-829-2684)**.

Reference:

1. COMIRNATY Original & Omicron BA.4/BA.5 Product Monograph. Pfizer Canada ULC.